



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,187	09/30/2005	Herbert Zech	ZECH ET AL 2 PCT	1329
25889	7590	07/28/2008		
COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER FORD, ALLISON M	
			ART UNIT	PAPER NUMBER
			1651	
			MAIL DATE	DELIVERY MODE
			07/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,187	Applicant(s) ZECH ET AL.	
	Examiner ALLISON M. FORD	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 and 23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

In response to the restriction requirement (mailed 1/11/2008), Applicants elected, with traverse, the species of:

- (b) blastocyte, as the species of embryo state
- (c) umbilical cord blood as the source of donor cell tissue
- (g) containing an exogenous vector that causes a lethal sensitivity to appropriate cultivation conditions in comparison to the particular wild type, as the genetic state of the embryo
- (i) containing an exogenous DNA sequence that causes a resistance to additives of culture media, as the genetic state of the donor cells
- (k) pig, as the species of non-human embryo
- (l) human, as the species of donor cells

The traversal is on the grounds that search and examination of the elected species would necessarily include a search for the non-elected species, thus a simultaneous search for all species would not be unreasonable. Furthermore, Applicants argue simultaneous search of all species would promote streamlined examination and compact prosecution. Still further, Applicants argue filing multiple patent applications would not serve public interest because of the fees involved and the burden upon the public which would be caused by searching through multiple patent files.

While these arguments have been fully considered, they are not found persuasive. For the reasons previously made of record, the disclosed species are not art recognized equivalents, and thus the species lack the same or corresponding special technical and fail to relate to a single general inventive concept under PCT Rule 13.1 and PCT Rule 13.2. Furthermore, Applicants are reminded that upon

Art Unit: 1651

allowance of a generic claim applicant is entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of the allowed generic claim, as provided by 37 CFR 1.141.

However, upon reconsideration, the following new grounds of restriction are required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19 and 23 (claims 1-4, 8-14, 16, 17 and 19 drawn to elected species), drawn to a method for producing cell lines.

Group II, claim(s) 1-19 and 23 (claims 1-4, 8-14, 16, 17 and 19 drawn to elected species), drawn to a method for producing individual organs.

In the instant case the methods of Inventive Groups I and II are considered to lack unity *a priori*, as the methods do not appear to share any subject matter common. Each of the claims which recite method steps appear to recite different steps for development of cell lines or development of individual organs. For example, in claim 1, it appears donor cells are *either* (i) cultivated under conditions that ensure development of the blastocyst (elected species) in stages in which newly formed lines having higher degrees of differentiation occur and then isolating the cell lines, or (ii) the blastocysts are transferred into a surrogate mother animal for differentiation of the cells into organs.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Art Unit: 1651

The election of an invention may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner wishes to point out that the current claims are found to be replete with indefinite and idiomatic language, to the extent that a meaningful interpretation of the claims is almost precluded. In claiming a method, the steps required to carry out the method must be clearly and positively specified. The steps must be set forth and correlated in a such a manner as to present a complete operative method. Review and correction of the claims, prior to subsequent examination, is strongly suggested.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Examiner, Art Unit 1651